

REMARKS

Claims 161-166 and 262-279 appear in this application for the Examiner's review and consideration. Applicants fully reserve their rights to prosecute the subject matter of any withdrawn claim or unclaimed subject matter in one or more continuation, continuation-in-part, or divisional applications.

Claim 165 stands rejected under 35 U.S.C. § 102(b) as anticipated by U.S. patent No. 5,891,891 to E. Benincasa ("the '891 patent") for the reasons set forth at page 3 of the Office Action. Applicants respectfully traverse.

It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986), *cert denied*, 480 U.S. 947 (1987). Although the use of additional references to confirm the contents of an allegedly anticipating reference is permitted, anticipation does not permit an additional reference to supply a missing claim limitation. *Teleflex, Inc. v. Ficosa North American Corp.*, 299 F.3d 1313 (Fed. Cir. 2002).

Under the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will be deemed to anticipate a subsequent claim if the missing element "is necessarily present in the thing described in the reference, and that is would be so recognized by persons of ordinary skill." *Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991). "Inherent anticipation requires that the missing descriptive material is necessarily present, not merely probably or possibly present, in the prior art." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295, 63 U.S.P.Q.2d 1597 (Fed. Cir. 2002).

The '891 patent fails to anticipate claim 165 because the reference fails to meet every element of the claimed invention. Claim 165 is dependent from claim 161 which recites a zolpidem hemitartrate characterized by an X-ray diffraction pattern having peaks at about 7.1, 9.5, 14.1, 19.6, and 24.5 ± 0.2 degrees two-theta. Claim 165 further recites a pharmaceutical composition comprising the 161 zolpidem hemitartrate, wherein the zolpidem hemitartrate is in the form of particles and a pharmaceutically acceptable carrier. The Office Action erroneously equates the '891 patent pharmaceutical composition with the composition of claim 165. The error resides in equating a non-crystal structure with the crystal particle recited in claim 165. As a dependent claim the pharmaceutical composition of claim 165 has particles which comprise zolpidem having the crystal structure of claim 161. The Office

Action mischaracterizes the claim 165 composition by ignoring the term “particle” and stating that “the instant liquid composition” would be the same as the pharmaceutical composition disclosed in the ‘891 patent. Although the zolpidem hemitartrate may exist as a particle in a liquid suspension or in a solid dosage form, nevertheless, zolpidem hemitartrate is still in a particle form. The claim reading by the Office Action completely ignores the term “particle” or its ordinary meaning in the art. This error is fatal to any anticipation argument grounded in the ‘891 patent.

Moreover, the ‘891 patent fails to enable one of ordinary skill in the art to obtain the particular crystal structure of the claim. As disclosed in the present invention, zolpidem hemitartrate may crystallize as one of several polymorphs. The general statement of the ‘891 patent fails to enable the skilled artisan to make the specific polymorph of the claim. In fact, the ‘891 patent provides a general description without any specific crystallization instructions.

Consequently, the ‘891 patent does not anticipate the present claims. Accordingly, the rejection of claim 165 under 35 U.S.C. § 102(b) as anticipated by the ‘891 patent cannot stand and should be withdrawn.

Claims 161-166 and 263-279 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for the reasons set forth on page 3 of the Office Action. Applicants respectfully traverse.

A claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought. *In re Swinehart*, 439 F.2d 210, 160 U.S.P.Q. 226 (C.C.P.A. 1971), *see also* MPEP 2173.01. Determining whether a claim is definite requires an analysis of whether one skilled in the art would understand the bounds of the claim when read in light of the specification. *Solomon v. Kimberly-Clark Corp.* 216 F.3d 1372, 55 U.S.P.Q.2d 1279 (Fed. Cir. 2000) citing *Personalized Media Communications, LLC v. ITC*, 161 F.3d 696, 705, 48 U.S.P.Q.2d 1180, 1888 (Fed. Cir. 1998) (emphasis added). If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more. *Id.* In other words, the definiteness of the claim language must be analyzed, not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. *Solomon v. Kimberly-Clark Corp.* 216 F.3d 1372, 55 U.S.P.Q.2d 1279 (Fed. Cir. 2000) citing *In re Moore*, 439 F.2d 1232, 169 U.S.P.Q. 236 (CCPA 1971).

The Office Action rejects the claims because of the use of the term “about.” The term, however, has been widely accepted as described in the MPEP. See MPEP 2173.05(b)(A). As early as 1968, the term “about” has been held to be clear, but flexible. *Ex parte Eastwood*, 163 U.S.P.Q. 316 (BD. App. 1968). As long as one of skill in the art who reads an X-ray diffraction pattern understands the variations inherent within the spectroscopic apparatus, the term “about” is sufficiently defined. Moreover, the claim itself provides guidance as to the meaning of about by including a peaks within a range of ± 0.2 degrees two-theta.

Thus, the rejection of claims 161-166 and 263-279 under 35 U.S.C. § 112, second paragraph, cannot stand and should be withdrawn.

Claims 161-166 and 263-279 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement for the reasons set forth on pages 3 and 4 of the Office Action. Applicants respectfully traverse.

As long as a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if not every nuance of the claims is explicitly described in the specification, then the adequate written description requirement is met. *In re Alton*, 76 F.3d 1168, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996). “*Ipsis verbis* disclosure is not necessary to satisfy the written description requirement of section 112.” *Fujikawa v. Wattanasin*, 93 F.3d 1559, 39 U.S.P.Q.2d 1895 (Fed. Cir. 1996).

The Office Action rejected claims 161-166 and 263-279 by taking an overly narrow reading of the specification without reading the claim in view of the entire specification. In fact, the Office Action demands *ipsis verbis* support, contrary to established law. The Office Action states that “the specification only discloses a zolpidem hemitartrate *Form D* ... which is a monohydrate or hemiethanolate (p. 18 of the specification).” Office Action p. 4. “The hydrate and the solvate thereof as recited in new claims 263, 268, and the compounds in the claims dependent thereon, are not found in the specification.” Office Action p. 4. The statements completely ignore the specification which also states: “[a]s used herein, the term “zolpidem hemitartrate” includes hydrates and solvates of zolpidem hemitartrate.” Specification p. 11, ll. 6-7. Accordingly, the hydrate and the solvate are contemplated within the term zolpidem hemitartrate and thus, described in the specification to the extent necessary to meet the burden under § 112, first paragraph. Thus, the rejection of

claims 161-166 and 273-279 under 35 U.S.C. § 112, first paragraph, cannot stand and should be withdrawn.

Accordingly, it is believed that claims 161-166 and 262-279 are now in condition for allowance, early notice of which would be appreciated.

If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same. No fee is believed to be due for the submission of this response. Should any fees be required, please charge such fees to Kenyon & Kenyon, LLP Deposit Account No. 11-0600.

Respectfully submitted,

Dated: 2/9/04

By: Craig L. Puckett
Craig L. Puckett (Reg. No. 43,023)

For: Patrick J. Birde (Reg. No. 29,770)

Kenyon & Kenyon LLP
Intellectual Property Department
One Broadway
New York, NY 10004
Tel: (212) 425-7000
Fax: (212) 425-5288